

SUMMARY OF PROPANIL RISK ASSESSMENT

May 20, 2002

Uses

- Propanil is an anilide herbicide registered for the selective post-emergent control of broadleaf weeds and grass in commercial settings. Propanil works by inhibiting normal photosynthesis. Propanil is also registered (but not currently marketed) for use on commercial sod farms. There are no existing or proposed residential uses of propanil products.
- Food Uses for propanil are rice, barley, oats and spring wheat. Registered uses on rice is limited to CA and the mid-southern states (AR, LA, MO, MS and TX) whereas use on barley, oats and spring wheat are geographically limited to the states of MN, MT, ND and SD.
- Usage on rice accounts for approximately ninety-nine percent (99%) of total U.S. (annual average) domestic usage of approximately 7 million pounds of active ingredient on a total of approximately 2 million acres treated. Fifty to seventy percent (50% to 70%) of the U.S. rice crop is treated with propanil.
- Available as an emulsifiable concentrate liquid (16.6-58% active ingredient (a.i.)), a water dispersable granule (or dry flowable) (59.6-81% a.i.), a soluble concentrate liquid (41.2-80.2% a.i.) and a flowable concentrate (41.2% a.i.) formulation.
- Applied as a broadcast treatment by groundboom sprayers and aerial equipment.

Human Health Effects

- Propanil has low acute toxicity, although primary eye irritation is observed in rabbits. Propanil has not been shown to cause dermal sensitization.
- EPA has not assessed acute dietary risk for propanil since no appropriate endpoint attributable to a single dose could be identified.
- The toxicity endpoint for the chronic dietary assessment is methemoglobinemia (decreases in hemoglobin, red blood cell count and/or packed cell volume) and is calculated using the Lowest Observed Adverse Effect Level (LOAEL) of 9 mg/kg/day from the chronic/carcinogenicity study in the rat (no NOAEL was identified).
- The FQPA Safety Factor of 10x was retained for chronic exposures based on increased susceptibility following pre- and post-natal exposure, the lack of a developmental neurotoxicity study; and neuroendocrine disruption in the rat.
- The total Uncertainty Factor (UF) used in the RfD derivation is 300x. The UF is 100x (10x for inter-species extrapolation and 10x for intra-species variability). An additional UF of 3x is applied for the use of a LOAEL instead of a NOAEL for an overall UF of

3,000x.

- The Agency has classified propanil into the category “*Suggestive evidence of carcinogenic potential by all routes of exposure, but not sufficient to assess human carcinogenic potential.*”

Risks

Dietary Risk from food treated with propanil is not of concern.

Drinking Water Risk is not of concern to most population subgroups.

- EPA estimates indicate a potential drinking water concern for children. However, the Agency believes that the concerns have been addressed by the conservative assumption (field trial residue levels) used in the chronic dietary (food) calculation. The Agency concludes that residues of propanil *per se* and its principle metabolic degradate 3,4-DCA (combined) are less than the estimated DWLOC and a conclusion can be drawn that no adverse toxicological effect will occur due to aggregate chronic exposure.

Residential Risk and **Aggregate Risk** are not of concern.

Occupational Risk is high.

- The risk to mixers, loaders and applicators handling and applying propanil using aerial and groundboom equipment is of concern for many occupational exposure scenarios, even with maximum personal protective equipment and risk reduction measures.
- A Restricted Entry Interval (REI) of 24 hours for rice and 18 days for turf are necessary to adequately address post-application reentry risks. Current propanil labels have a 24 hour REI.

Environmental Fate and Effects

Risks

Avian Risk is very slight to moderate.

- Propanil is moderately toxic to birds on an acute oral basis and very slightly toxic on a subacute dietary basis.
- Use on rice is expected to slightly exceed the level of concern (LOC) for acute and chronic risks to birds (risk includes endangered species).
- There are no reported incidents on birds.

Aquatic Species Risk is low to moderate.

- Propanil is categorized as slightly to moderately toxic to freshwater fish and moderately

toxic to freshwater invertebrates, estuarine/marine fish and estuarine/marine invertebrates.

- LOCs are slightly exceeded for the small grain and turf uses.
- There are no data to assess chronic risk to estuarine invertebrates and fish (including endangered species).
- There are no reported incidents on fish.

Mammalian Risk is low.

- Propanil is classified as slightly toxic to small mammals on an acute oral basis.
- The labeled use of propanil on turf is expected to slightly exceed the LOC for acute and chronic risks to mammals (risks include endangered species).

Nontarget Plant and Insect Risk is low to not of concern.

- Since propanil is practically nontoxic to the honeybee, the Agency assumes that its use on rice and turf will not exceed the any LOC to other nontarget insects. The Agency suspects that the major degradate of propanil, 3,4-DCA, may cause adverse effects on nontarget insects. However, EPA's concerns about 3,4-DCA are based upon limited data. In order to adequately assess the risks of 3,4 DCA, more environmental fate and ecological toxicity data are needed.
- The Agency assumes risk to nontarget plants from propanil use on rice due to its herbicidal mode of action, the amount of spray drift that occurs from application, and one reported incident of plant damage following aerial application of propanil to rice fields in Craighead, AR, in the absence of chemical-specific data.